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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,358	10/02/2003	Karine Vidal	88265-6852	8288
29157 7590 09/14/2007 BELL, BOYD & LLOYD LLP P.O. Box 1135 CHICAGO, IL 60690			EXAMINER KAM, CHIH MIN	
			ART UNIT 1656	PAPER NUMBER
			NOTIFICATION DATE 09/14/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

## Office Action Summary

**Application No.**

10/676,358

**Applicant(s)**

VIDAL ET AL.

**Examiner**

Chih-Min Kam

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-28 is/are pending in the application.
- 4a) Of the above claim(s) 12-16 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17,21 and 22 is/are allowed.
- 6) ☒ Claim(s) 18-20,23-25,27 and 28 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 12-28 are pending.

Applicants' amendment filed July 5, 2007 is acknowledged. Applicant's response has been fully considered. Claims 17 and 19 have been amended, claims 1 and 3-11 have been cancelled, and new claims 20-28 have been added. Claims 12-16 are non-elected inventions and withdrawn from consideration. Therefore, claims 17-28 are examined.

### **Withdrawn Claim Objections**

2. The previous objection to claims 3-11 is withdrawn in view of applicants' cancellation of the claims in the amendment filed July 5, 2007.

### **Withdrawn Claim Rejections - 35 USC § 102**

3. The previous rejection of claims 1 and 19 under 35 U.S.C. 102(b) as being anticipated by Simonet *et al.* (Cell 89, 309-319 (1997)), is withdrawn in view of applicants' cancellation of the claim, applicants' amendment to the claims, and applicant's response at page 5 in the amendment filed July 5, 2007.

4. The previous rejection of claims 1 and 19 under 35 U.S.C. 102(e) as being anticipated by Yano *et al.* (U.S. Patent 6,693,175), is withdrawn in view of applicants' cancellation of the claim, applicants' amendment to the claims, and applicant's response at page 5 in the amendment filed July 5, 2007.

### ***New Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Simonet *et al.* (Cell 89, 309-319 (1997)).

Simonet *et al.* teach osteoprotegerin (OPG) is a secreted glycoprotein that regulates bone resorption and has 4 potential sites of N-linked glycosylation (page 310, left column; Fig 1B), and the mature OPG (residues 22-401 of human species shown in Fig. 1B) has the same amino acid sequence as SEQ ID NO:1. The OPG is recombinantly synthesized as an approximately 55 kDa monomer within the cell and is converted to disulfide-linked dimer of approximately 110 kDa (the paragraph bridged pages 310 and 311; page 317, right column), which is approximately 130 kDa since the specification does not specifically define the term “approximately”. Although the claim recites osteoprotegerin is obtained from human or bovine milk or colostrum, the claimed osteoprotegerin is not different from the osteoprotegerin made recombinantly as shown in the reference (claim 20). MPEP 2113 states that “Even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself, the patentability of a product does not depend on its method of production.”

6. Claims 18, 19, 23-25, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Goto *et al.* (EP 0816380, published on January 7, 1998; listed in IDS of 3/18/04).

Goto *et al.* teach an osteoclastogenesis inhibitory factor (OCIF, another name for osteoprotegerin, OPG) can be isolated and purified from fibroblast medium or produced recombinantly, and has apparent molecular weight of 60 kDa as a monomer and of 120 kDa as a dimer (page 2, line 48-page 3, line 7; Figs. 6 and 7; Example 4, 17 and 18), where N-linked sugar chains of OCIF are removed and the deglycosylated OCIF has apparent molecular weight of 40

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kDa (Example 19, Fig. 8). The reference also teaches the preparation of a pharmaceutical composition by mixing a therapeutically effective amount of OCIF and a pharmaceutically acceptable carrier such as a buffer, a stabilizer or a solubilizing agent (page 5, lines 1-13; claims 18, 19, 23-25 and 27), and the composition comprising OCIF may be administered by oral (claim 28). Since the specification does not specifically define the term "approximately", an OCIF with a molecular weight of 120 kDa meets the criteria of the limitation (i.e., OCIF having a molecular weight of approximately 130 kDa). Although the claim recites osteoprotegerin is obtained from human or bovine milk or colostrum, the claimed osteoprotegerin is not different from the osteoprotegerin made recombinantly as shown in the reference (i.e., having same molecular weight). MPEP 2113 states that "Even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself, the patentability of a product does not depend on its method of production." Since the pharmaceutical composition of Goto *et al.* contains a therapeutically effective amount of OPG, it would be expected that the amount of OPG would be effective to assist in formation of lymphoid tissues and regulation of immune responses in a subject, which meets the criteria of the claimed pharmaceutical composition.

### ***Claim Objections***

7. Claim 26 is objected to because the claim is dependent form a rejected claim.

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***Conclusion***

8. Claims 18-20, 23-25, 27 and 28 are rejected, claim 26 is objected to; and it appears that claims 17, 21 and 22 are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner



CHIH-MIN KAM  
PRIMARY EXAMINER

CMK

September 7, 2007